Message

From: Williams, Jonathan R. [williams.jonathanr@epa.gov]
Sent: 6/5/2019 7:40:33 PM
To: Perron, Monique [Perron.Monique@epa.gov]; Walls, Cassi [Walls.Cassi@epa.gov]; Dawson, Jeffrey [Dawson.Jeff@epa.gov]; Lowe, Kelly [Lowe.Kelly@epa.gov]; Crowley, Matthew [Crowley.Matthew@epa.gov]; Villanueva, Philip [Villanueva.Philip@epa.gov]; Zinn, Nicole [Zinn.Nicole@epa.gov]; Olinger, Christine [Olinger.Christine@epa.gov]; Vogel, Dana [Vogel.Dana@epa.gov]; Wilbur, Donald [Wilbur.Donald@epa.gov]; Reaves, Elissa [Reaves.Elissa@epa.gov]; Smith, Charles [Smith.Charles@epa.gov]; Friedman, Dana [Friedman.Dana@epa.gov]; VanDeusen, Brian [vandeusen.brian@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Dole, Timothy [Dole.Timothy@epa.gov]; mark.ledson@syngenta.com; Leighton, Timothy [Leighton.Timothy@epa.gov]; Flack Sheila USGR [sheila.flack@syngenta.com]; paul.hinderliter@syngenta.com; doug.wolf@syngenta.com; Ramanarayanan Tharacad USGR [Tharacad.Ramanarayanan@SYNGENTA.COM]; EJerkins@knoellusa.com; carrie.fleming@corteva.com; Edward.Scollon@valent.com; shakil.saghir@scotts.com; jeffrey.holmsen@basf.com; patrick.havens@corteva.com; curt.lunchick@bayer.com; jeff@risksciences.net; rreiss@exponent.com; tom@sciencestrategies.com; rtestman@gplabs.com; pat.havens@corteva.com; a.hewitt@uq.edu.au; hwthistle@gmail.com; Brad.Fritz@ARS.USDA.GOV; robert.mitkus@basf.com
CC: driverjh@comcast.net; Khan, Faruque [Khan.Faruque@epa.gov]
Subject: RE: PSD Data Meeting
Attachments: PSD meeting agenda_6.10.19.docx; Agency Issue Paper_December SAP.pdf; MRID 50610402.pdf; MRID 50610404.pdf

Good afternoon,

Thank you to those who have responded to EPA's invitation to the PSD Meeting on Monday, June 10th at 12:30 pm. Please read this email carefully.

Attached please find an agenda for the meeting, which also includes some considerations to think about prior to the meeting. If you are not familiar with the December Scientific Advisory Panel (SAP) meeting that discussed one of the approaches to refine inhalation risk assessment using human relevant PSDs, the package can be found at https://www.epa.gov/sap/meeting-materials-december-4-6-7-2018-scientific-advisory-panel. The most relevant documents for the PSD Meeting include the agency's issue paper, Syngenta's submission on particle size characterization (MRID 50610404), and Syngenta's source to outcome paper (MRID 50610402). For convenience, we have attached these documents.

For those of you representing outside organizations, please arrive in the lobby of the south tower of the Potomac Yard facility (2777 Crystal Dr, Arlington, VA 22202) **between noon and 12:15 pm** to allow time for security screening.

All visitors must provide federally accepted ID to enter the building (such as a driver's license or passport). Anyone without ID will be denied entry without exception.

I will meet visitors in the lobby to escort them to the meeting room on the fourth floor. Please contact me (703-347-0670) or Nicole Zinn (703-308-7076) for questions or issues on the day of the meeting.

Parking is available in the rear of the building, off of S Potomac Ave. Limited public parking may also be available on Crystal Dr or across Rt 1 (Jefferson Davis Hwy) on Ft Scott Dr. EPA is not responsible for visitors' vehicles.

Thank you,
Jon Williams

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Office of Pesticide Programs

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U.S. Environmental Protection Agency
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703-347-0670

-----Original Appointment-----
From: Williams, Jonathan R.
Sent: Friday, May 17, 2019 9:11 AM
To: Williams, Jonathan R.; Perron, Monique; Walls, Cassi; Dawson, Jeffrey; Lowe, Kelly; Crowley, Matthew; Villanueva, Philip; Zinn, Nicole; Olinger, Christine; Vogel, Dana; Wilbur, Donald; Reaves, Elissa; Smith, Charles; Friedman, Dana; VanDeusen, Brian; Anna Lowitt (Lowit.Anna@epa.gov); Dole, Timothy; mark.ledson@syngenta.com; Leighton, Timothy; Flack Sheila USGR; paul.hinderliter@syngenta.com; doug.wolf@syngenta.com; Ramanarayanan Tharacad USGR; EJerkins@knoellusa.com; carrie.fleming@corteva.com; Edward.Scollon@valent.com; shakil.saghir@scotts.com; jeffrey.holmsen@basf.com; patrick.havens@corteva.com; curt.lunchick@bayer.com; jeff@risksciences.net; rreiss@exponent.com; tom@sciencestrategies.com; rtestman@gplabs.com; pat.havens@corteva.com; a.hewitt@uq.edu.au; hwthistle@gmail.com; Brad.Fritz@ARS.USDA.GOV; Robert Mitkus
Cc: driverjh@comcast.net; Khan, Faruque
Subject: PSD Data Meeting
When: Monday, June 10, 2019 12:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: US EPA OPP 2777 Crystal Dr Arlngton, VA 22202; Room: 4370/80

The Office of Pesticide Programs (OPP) has received several inquiries regarding approaches to refine inhalation risk assessment that rely on human relevant particle size distributions (PSDs). However, OPP requires additional information to be able to employ these refined methodologies. OPP has scheduled this meeting to discuss the information needed to ensure appropriate scientifically supportable PSDs are identified and discuss any potential challenges with generating these data.

In December 2018, a case study for the refinement of the inhalation risk assessment of a respiratory contact irritant was reviewed by a Scientific Advisory Panel (SAP)[1]. This approach utilizes computational fluid dynamic (CFD) modeling to estimate particle deposition in the respiratory tract using human relevant PSDs. For the purposes of the SAP meeting, a mathematically-derived PSD for inhalable particles for spray applicators was used; however, additional support would be needed to use this PSD for human health risk assessments supporting regulatory decisions. The case study only considered spray applicator exposures using PSD data from a chamber study meant to represent groundboom applications. Additional information is needed to demonstrate that the parameters/conditions in the chamber study (e.g., wind speed, pressure, distance from nozzle to collector, etc) are truly representative of conditions occurring during an actual groundboom application. Furthermore, in order to apply this case study approach to other application types (e.g., airblast, aerial, backpack, paint-guns) and mixer/loader scenarios (e.g., mixing product concentrate with water), data will be needed to identify PSDs for those other scenarios. Alternatively, data demonstrating that one generic PSD is scientifically defensible and applicable for all exposure scenarios would also be acceptable.

OPP has also received several requests to use the multiple path particle dosimetry (MPPD) model rather than the regional deposited dose ratio (RDDR) approach as a method to refine inhalation risk assessment. Similar to RDDR, the MPPD model can account for differences between laboratory animal and human airways; however, there is the potential to modify most of the parameters in MPPD. Unless parameters are changed from the default values currently used in the RDDR program, MPPD will provide outputs similar to those obtained using RDDR; therefore, simply moving to the MPPD model will not resolve inhalation risks of concern.

[1] https://www.epa.gov/sap/fifra-scientific-advisory-panel-meetings

MPPD does have the potential to incorporate different PSDs and thus may provide a level of refinement for inhalation risk assessment. Current proposals have described the calculation of an adjustment factor that takes into account differences in deposition rates in the human respiratory tract using the PSD from an *in vivo* laboratory animal study and human relevant PSDs. The adjustment factor would then be used to adjust a point of departure derived from an *in vivo* laboratory animal study and calculate a human equivalent concentration (HEC). However, similar to the case study described above, this proposed approach to refine inhalation risk assessments would also require human relevant PSDs for each application type/exposure scenario of interest.

It should be noted, however, that the MPPD model has not yet been subjected to peer review in a process consistent with other models used by OPP and OPP would be required to take MPPD thru the peer review process before application in our risk assessments. In addition to this review, OPP will need to determine appropriate default parameter values (e.g., breathing rates) and model selections (e.g., symmetric vs. asymmetric) that are scientifically supportable and health protective for inhalation risk assessment.

OPP is asking registrants to provide data and information to support the human relevant PSDs needed to consider and implement the proposed refinement approaches. As mentioned above, data are needed to determine whether the same PSD could be applied for different application types/exposure scenarios or if scenario-specific PSDs are needed. OPP will need PSDs for all scenarios of interest to registrants. Ideally, default or generic PSDs would be identified that could be used across chemicals. OPP does not have a standard protocol at this time for generating data to support human relevant PSDs; however, registrants may consider examining existing data sets and literature information before designing and conducting new studies. If new exposure studies need to be conducted with human subjects, the protocol(s) and final studies may require review of the Human Studies Review Board (HSRB) to ensure data and studies are in accordance with the Human Studies Rule.

If PSD data are not identified/collected, human relevant PSDs cannot be incorporated and using these potential refinements will not be a feasible option to resolve inhalation risks of concern. Consequently, OPP would continue to use the existing inhalation risk assessment methodology that will likely result in risks of concern for chemicals where they have already been identified.

For technical questions related to this meeting, please contact Cassi Walls (walls.cassi@epa.gov). For inquiries regarding the upcoming meeting logistics, please contact Jon Williams (williams.jonathanr@epa.gov).